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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/334,858	06/16/1999	ALFRED E. MANN	PD-0294	5808

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EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER

3763

DATE MAILED: 10/07/2002

AM

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/334,858	MANN ET AL.
	Examiner Ann Y. Lam	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 June 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 35-55,65-72 and 86-145 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 35-55,65-72 and 86-145 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 140-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly added claims 140-145 are dependent on claim 73, which Applicant has cancelled. Applicant is requested to amend or cancel claims 140-145.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**2.** Claims 51-55, 65, 67-69, 104-108 and 134-139 are rejected under 35 U.S.C. 102(e) as being anticipated by Gross et al., 5,800,420.

As to claims 51 and 55, Gross discloses a drive mechanism to operatively couple with a reservoir to infuse a liquid into a body; a housing (11) adapted for use on an exterior of the body, see column 2, lines 18-29, and column 14, lines 58-64, wherein the housing is sized to contain at least a portion of a reservoir (12), wherein the drive mechanism is contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir, and wherein the housing is sized to fit in a clothing pocket, see column 2, line 20; a processor coupled to the housing, see column 1, line 47; a keypad coupled to the housing to determine an estimate of remaining battery power, see column 18, lines 48-50 and column 19, lines 1-4; and an indication device (60) to indicate the estimate of remaining battery power, see column 19, lines 1-4.

As to claims 52, 54, Gross also discloses a memory to store at least two personal delivery patterns, including two basal rate profiles, see column 1, lines 25-28, and a keypad and an indication device as claimed, see column 1, lines 28-29 and column 9, lines 19-23.

As to claim 53, a receiver coupled to the housing for receiving remotely generated commands is disclosed in column 2, lines 16-21, (the commands here are

considered to be commands from the sensor in column 2, line 16). Alternately, the claimed receiver is considered to be remote from a keypad, see column 9, lines 19-24.

As to claims 65, a vibration alarm provides one or more tactile sensations to the user in response to a low reservoir alert, see column 18, line 21. The audio alarm is considered to be a vibration alarm providing a tactile sensation, as claimed by Applicant.

As to claim 67, the vibration alarm provides one or more tactile sensations to the user in response to a communication from a remote commander, see column 18, lines 17-25.

As to claim 68, the vibration alarm provides one or more tactile sensations to the user in response to one or more commands to change one or more operations of the external infusion device, see column 18, lines 17-25.

As to claim 69, the vibration alarm provides one or more tactile sensations to the user during a period that the infusion device is in a suspend mode, see column 18, lines 17-29.

As to claims 104-108 and 134-139, the housing is sized to be worn on a belt, under clothing in an unobtrusive manner, against the skin, or in a pocket, see column 2, lines 18-21.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 35-43, 70-72, 86-91, 104-133 and 140-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al., 5,800,420, in view of DeCant, Jr. et al., 4,443,218.

Gross discloses the invention substantially as claimed. More specifically, Gross discloses a drive mechanism to operatively couple with a reservoir to infuse a liquid into a body; a housing (11) adapted for use on an exterior of the body; see column 2, lines 18-29, and column 14, lines 58-64, wherein the housing is sized to contain at least a portion of a reservoir (12), wherein the drive mechanism is contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir, and wherein the housing is sized to fit in a clothing pocket, see column 2, line 20; a processor coupled to the housing, see column 1, line 47.

However, Gross does not disclose a bolus estimator as claimed by Applicant.

However, DeCant discloses a bolus estimator used in conjunction with a processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63. Also, it is inherent that there is an indication device to indicate when an amount of fluid to be infused has

been calculated, since the DeCant device allows the patient to change the bolus rate to match his caloric intake during a meal.

As to claim 36, the bolus estimator includes the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 37, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claims 38 and 39, the liquid to be infused is insulin, and the material to be ingested is carbohydrates, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 40, the bolus estimator includes a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator, see column 9, lines 11-17. The program allowing only the physician's programmer is considered to be the lockout to prevent the calculation of a bolus.

As to claim 41, the supplied values are codes representing a carbohydrate value of specific foods, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 42, the supplied values are codes representing a carbohydrate value of specific foods, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 43, it is inherent that there is a duration factor to determine a valued of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of fluid to be infused, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 58, the remote commander is considered to be portable.

As to claim 59, the transmitter wirelessly transmits commands to the receiver.

As to claims 60 and 61, remote commander is considered to have a unique identification code, and the processor is capable of storing the unique identification code.

As to claim 62, the remote commander establish non-line of sight communication with the external infusion device see column 8, 53-63, column 13, lines 3-11.

As to claim 63, the receiver is considered to include a standby mode, wherein the receiver does not receive, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 64, the receiver is considered to periodically become active, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claims 70-72, at least two personal delivery patterns are programmable by a user, see column 2, lines 21-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bolus estimator as taught by DeCant Jr. et al., in the

Gross et al. device, to infuse medication at a delivery depending upon the patient's requirements

4. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al., 5,800,420, in view of Gargano et al., 5,814,015.

Gross discloses the invention substantially as claimed, except for the vibration alarm in response to a low reservoir alert.

Gargano discloses an alarm in response to a low reservoir alert, see column 20, line 11. It would have been obvious to provide an alarm in response to a low reservoir alert as taught by Gargano as would be desirable in a pump device.

5. Claims 44-50 and 92-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al., 5,800,420, in view of Dent, 5,609,060.

Gross discloses the invention substantially as claimed, see above. However, Gross does not disclose a vibration alarm capable of assisting in removing gas bubbles from the fluid in the reservoir during priming of the external infusion device.

Dent discloses a priming operation wherein vibration is applied to the blood channel as the pump is driven at a constant speed, thereby removing bubble from the inner wall of the channel, see column 2, lines 8-14. It is inherent that there is a vibration device.

It would have been obvious to provide a vibration device to remove bubble, as taught by Dent, on the Gross pump, as would be desirable before using the medical pump on a patient.

***Response to Arguments***

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection. Gross discloses a pump as claimed that is sized to be worn on a belt or under clothing.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Worthington et al., 5,822,715, discloses a device to calculate data relating to insulin doses administered to a patient.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
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A.L.   
September 28, 2002